PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P60515/001	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/04078	International filing date *(day/month/year)* 23.09.2003	Priority date *(day/month/year)* 23.09.2002
International Patent Classification (IPC) or both national classification and IPC C07D311/80		
Applicant GW PHARMA LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.03.2004	17.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Seelmann, I Telephone No. +49 89 2399-7480

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04078

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-54 as originally filed

Claims, Numbers

1-91 as originally filed

Drawings, Sheets

1-21 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 55-90

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 55-90

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-27, 91 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-54,91
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-54,91
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-54,91
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

1. PRIOR ART

Reference is made to the following documents:

D1: US-B1-6365416
D2: US-A1-2002086438
D3: JACS, 93, 1971, 217-224

2. NOVELTY

The subject-matter of the claims is considered to be novel (Article 33(2) PCT). The essential difference between the claimed method and those of D1 to D3 resides in the specific sequens of the purification steps: Extraction followed by chromatography followed by two re-crystallisation steps, one in a more polar solvent and the second in a less polar solvent than the cannabinoid to be purified. D1-D3 disclose different methods for the isolation and/or purification of cannabinoids from plant material. D1 discloses a method for the isolation of THC by extraction followed at least by a low pressure flash distillation and a chromatography (claim 1 and examples 1-11). D2 discloses a method for the isolation of THC and THCA by extraction followed at least by a chromatography on alumina (claim 1 and examples 13-26 for THCA). D3 discloses i.a. a method for the isolation of CBG and CBC by extraction followed by repeated chromatography (compounds Va and VI, page 223, left col., line 10-35).

3. INVENTIVE STEP

The subject-matter of the claims can be considered as involving an inventive step (Article 33(3) PCT).

The documents D1 to D3 are regarded as being the closest prior art to the subject-matter of claim 1. They disclose methods for the isolation and/or purification of cannabinoids from plant material. D1 discloses a method for the isolation of THC by extraction followed at least by a low pressure flash distillation and a chromatography (claim 1 and examples 1-11). D2 discloses a method for the isolation of THC and THCA by extraction followed at least by a chromatography on alumina (claim 1 and examples 13-26 for THCA). D3 discloses i.a. a method for the isolation of CBG and CBC by

extraction followed by repeated chromatography (compounds Va and VI, page 223, left col., line 10-35).

The technical problem for claims 1-27 and 91 is seen in the provision of an alternative method for the isolation/purification of cannabinoids.

In view of the experimental part and the other information as given in the description, it can be assumed that this problem has been solved by the claimed method.

The prior art D1-D3 gives no information, which would motivate a man skilled in the art to combine different separation techniques in the way as in the present invention. Even the combination of the subject-matter of the prior art documents would not lead to the claimed invention.

It should be noted that the term substantially as i.a. in "substantially pure" renders the scope of the claims unclear.